UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION	MDL No. 2642 (JRT)
THIS DOCUMENT RELATES TO: *David Butkiewicz v. Bayer Corp., Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma A.G.,* and *Bayer, A.G.* Case No. 0:19-cv-01602-JRT.	**MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS** Master Docket Case No. 0:15-md-02642

Patrick Francis Bradley, **CLIFFORD LAW OFFICES**, 120 North LaSalle Street, Suite 3100, Chicago, IL 60602, for plaintiff.

Andrew Keith Solow, **ARNOLD AND PORTER KAY SCHOLER LLP**, 250 West 55th Street, New York, NY 10019, for defendants.

Defendants, manufacturers of the brand-name drug Cipro, filed a Motion to Dismiss, asserting that each of Plaintiff David Butkiewicz's claims alleged only injuries related to his use of ciprofloxacin, the generic equivalent of Cipro, which Defendants did not manufacture, market, or distribute. Butkiewicz, a resident of Illinois, contends that he and his prescribing physician relied on the ciprofloxacin label created by Defendants, as required by federal law, which failed to adequately warn of the risk of peripheral neuropathy as a side effect of the drug. Therefore, Butkiewicz argues that Defendants breached their duty to him under Illinois common law, and that he was injured by their

negligent and fraudulent labeling. Defendants disagree and urge the Court to reject Butkiewicz's theory of liability. Defendants posit that, although the Illinois Supreme Court has not addressed whether brand-name manufacturers may be liable for injuries caused by their warning labels when the label is affixed to a generic version of the drug, it would likely find that such claims are not viable.

Defendants are correct that Butkiewicz's strict liability and product liability – failure to warn claims fail as a matter of law because Defendants did not manufacture or distribute ciprofloxacin, and Butkiewicz's warranty claims fail because the parties were not in privity. Yet Butkiewicz may assert that Defendants are liable for his reliance-related injuries under theories of negligence, misrepresentation, and fraud with respect to their ciprofloxacin warning label. Under Illinois law, claims related to injuries caused by information about a product are distinct from product liability claims, and Defendants have a duty to all consumers who foreseeably rely on their warning label, irrespective of whether the consumer uses the brand name or generic form of the drug.

Accordingly, the Court will grant Defendants' Motion to Dismiss as it relates to Butkiewicz's strict liability, product liability – failure to warn, and breach of express and implied warranty claims, but will deny Defendants' Motion as it relates to Butkiewicz's remaining claims because they are cognizable and plausibly alleged.

BACKGROUND

I. FACTUAL BACKGROUND

Plaintiff David Butkiewicz was prescribed ciprofloxacin, a fluoroquinolone antibiotic, and used it as directed, (Compl. ("Individual Complaint") ¶¶ 30, 34, June 4 2019, Docket No. 1), from February to June 2013, (2nd Am. Compl. ("Amended MDL Short-Form Complaint") ¶¶ 8–9, Apr. 27, 2020, Docket No. 30).[1] Butkiewicz developed irreversible peripheral neuropathy. (Individual Compl. ¶ 3.) Due to misrepresentations by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG, and Bayer AG (collectively, "Defendants") in the ciprofloxacin warning label, Butkiewicz and his physicians did not recognize that he was suffering from permanent peripheral neuropathy caused by ciprofloxacin. (*Id.* ¶¶ 61–62.)

Butkiewicz alleges that Defendants failed to appropriately and adequately inform consumers and their physicians of the serious and dangerous risks of irreversible peripheral neuropathy associated with the use of Cipro and ciprofloxacin. (2nd Am. Master Compl. ("MDL Master Complaint") ¶ 68, Aug. 12, 2016, MDL No. 15-2642, Docket

[1] Butkiewicz initially alleged that he used brand-name Cipro, (*see* Compl. ¶¶ 1–2, June 4, 2019, Docket No. 1), but has since clarified that he used generic ciprofloxacin, (*see* 2nd Am. Compl. ¶ 9, Apr. 27, 2020, Docket No. 30.) The Court therefore treats all of Butkiewicz's allegations as generics-related claims. Additionally, the Court considers allegations from Butkiewicz's Individual Complaint in tandem with allegations in the MDL Master Complaint and Short Form Complaint, since cases consolidated for multi-district litigation pre-trial proceedings retain their separate identities. *See Gelboim v. Bank of America Corp.*, 574 U.S. 405, 413 (2015).

No. 241). The ciprofloxacin label used from September 2004 to August 2013 indicated that only "rare" cases of peripheral neuropathy had been reported in patients receiving quinolones, and the label did not explicitly include ciprofloxacin as among the drugs posing a risk of peripheral neuropathy. (MDL Master Compl. ¶ 89.) Because of the inadequate label, patients received fluoroquinolones, such as ciprofloxacin, instead of acceptable and adequate non-fluoroquinolone antibiotics. (*Id.* ¶¶ 96–97.)

On August 15, 2013, an updated warning label and accompanying safety information was issued for ciprofloxacin, which included a warning about the risk of rapid onset, irreversible peripheral neuropathy. (*Id.* ¶ 90.)

However, Defendants knew peripheral neuropathy and related symptoms were among the most common side effects of fluoroquinolones, including ciprofloxacin, for more than a decade prior to the August 2013 label change. (*Id.* ¶¶ 120, 123, 139.) Despite this knowledge, Butkiewicz alleges, Defendants recklessly and intentionally misled patients and physicians from September 2004 through August 2013, (*id.* ¶¶ 152, 156), by aggressively marketing fluoroquinolones and concealing the risks through misrepresentations and omissions, (*id.* ¶¶ 126–27.)

Defendants, through paid medical consultants, allegedly "fraudulently and intentionally polluted the scientific literature related to the safety and efficacy" of ciprofloxacin. (*Id.* ¶ 231 (listing allegedly false statements about ciprofloxacin).) For example, a consultant named Peter Ball stated that, "Ciprofloxacin is well tolerated; the

incidence of adverse events is low and serious adverse events are rare." (*Id.*) In 2001, Defendants, through Glenn Tillotson, a Bayer director and co-developer of Cipro, also allegedly sought to downplay the significance of the first major study finding peripheral neuropathy to be a permanent side effect of Cipro. (*Id.* ¶ 232.)

Butkiewicz asserts that Defendants intended consumers and physicians to rely on the misinformation in the ciprofloxacin warning label, (*id.* ¶ 164), and that he and his physician did so rely, (Individual Compl. ¶¶ 61–62.) Butkiewicz therefore alleges that his injuries were the direct and proximate result of Defendants' negligence, misrepresentations, and fraud in creating the ciprofloxacin warning label. (*See, e.g.*, MDL Master Compl. ¶¶ 212, 246, 254, 263.)

II. PROCEDURAL BACKGROUND

Butkiewicz filed a Complaint against Defendants in the Northern District of Illinois on June 4, 2019. (Individual Compl.) On June 18, 2019, Butkiewicz's case was transferred to the District of Minnesota for pretrial proceedings as part of Multidistrict Litigation ("MDL") No. 2642. (Conditional Transfer Order, June 18, 2019, Docket No. 4.) Butkiewicz completed the individual MDL Short Form Complaint on April 13, 2020. (Am. Compl., Apr. 13, 2020, Docket No. 26.)

On April 27, 2020, Butkiewicz filed an Amended MDL Short Form Complaint, clarifying that he used generic ciprofloxacin. (Am. MDL Short Form Compl. ¶¶ 8–9.) Butkiewicz identified Illinois law as supporting his generics-related claims against the

brand-name manufacturers.[2] (*Id.* ¶ 9.) Butkiewicz asserts claims for Strict Liability, Product Liability – Failure to Warn, Negligence, Breach of Express Warranty, Breach of Implied Warranty, Fraud, Negligent Misrepresentation, Fraudulent Concealment, and Violation of Consumer Protection/Consumer Fraud Law. (*Id.* ¶ 17.)

On August 14, 2020, Defendants filed a Motion to Dismiss Butkiewicz's Amended MDL Short Form Complaint pursuant to Rule 12(b)(6), arguing Butkiewicz failed to state a claim against Defendants under Illinois law. (Mot. Dismiss, Aug. 14, 2020, Docket No. 34.)

DISCUSSION

I. STANDARD OF REVIEW

In reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court considers all facts alleged in the complaint as true to determine if the complaint states a "claim to relief that is plausible on its face." *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Although the Court accepts the complaint's factual allegations as

[2] The MDL Master Complaint, incorporated by reference in Butkiewicz's Amended MDL Short Form Complaint, alleges Defendants may be liable for generics-related claims because "[i]n *Dolin v. SmithKlineBeecham Corp.*, 62 F. Supp. 3d 705, 720–21 (N.D. Ill. 2014), the court held that under Illinois common law, a brand-name manufacturer owes a duty of care to the generic consumer." (MDL Master Compl. ¶ 113.)

true and construes the complaint in a light most favorable to the plaintiff, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986). In other words, a complaint "does not need detailed factual allegations," but it must include more "than labels and conclusions, and a formulaic recitation of a cause of action's elements" to meet the plausibility standard. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

II. ANALYSIS

A. Federal Duty of Sameness and Preemption

The obligations and limitations of brand-name and generic drug manufacturers are set by federal law. Most important here, the Hatch-Waxman Amendments streamlined the approval process for generic equivalents of brand-name drugs that had already been approved by the FDA. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612–13 (2011) (citing 21 U.S.C. § 355). The simplified generics approval process requires the generic drug's design and warning label to be identical to the brand-name version at the time of approval. *Id.* at 613.

In *Mensing*, the Supreme Court addressed whether generic manufacturers may change their labels after initial FDA approval. *Id.* The Supreme Court held that, unlike brand-name drugs, generic drug manufacturers cannot unilaterally change their warning labels after initial approval, since federal law requires that generic drug labels be the same as the corresponding brand-name drug label at all times. *Id.* at 618. As such, state law

tort claims against generic drug manufacturers asserting they have a duty to provide stronger warning labels are preempted by federal law. *Id.* However, state tort claims against brand-name manufacturers asserting they have a duty to provide stronger, adequate warnings are not preempted by federal law because federal regulations permit brand-name manufacturers to unilaterally revise drug warnings. *See Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

B. Brand-Name Manufacturer Warning Label Liability

As a result of the federal "duty of sameness," which requires generic drug manufacturers to use warning labels created by brand-name manufacturers, *see Mensing*, 564 U.S. at 618–19, consumers have sought to hold brand-name manufacturers liable under state tort law for injuries caused by defects in generic drug labels. Many courts, however, have been unreceptive to these claims, concluding that brand-name manufacturers should not be held liable for injuries caused by drugs they did not produce, irrespective of how the claim is styled, whether as a products liability claim or a negligence or misrepresentation claim. *See Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."). Courts also frequently cite policy concerns about the potential effects that permitting such claims might have on the pharmaceutical industry overall. *See, e.g.*, *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*,

756 F.3d 917, 944 (6th Cir. 2014) ("[T]here are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs.").

Many cases rejecting brand-name manufacturers' liability for warning labels on generic products rely, in part, on the Fourth Circuit's decision in *Foster v. American Home Products Corp*, which held that "a name brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from use of another manufacturer's product[.]"[3] 29 F.3d 165, 167 (4th Cir. 1994). The *Foster* court reasoned that "in this case the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions." *Id.* at 168. The court also concluded that, even if it considered the negligent misrepresentation claim on the merits under Maryland law, it would fail because "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." *Id.* at 171.

Based on *Foster*, a two-part analysis emerged. Courts first examine whether the applicable state law requires all claims brought by a generic consumer against a brand-name manufacturer to be treated as products liability claims. If not, courts next examine

---

[3] *See, e.g.*, *Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 401 (6th Cir. 2013) (noting *Foster* as the "leading case on this issue"); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092 (8th Cir. 2013) (citing *Foster* to support rejecting the existence of a duty between brand-name manufacturer and generic consumer); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–85 (10th Cir. 2013) ("Since *Foster* was decided, every federal court to address this issue . . . has consistently followed.").

whether a brand-name manufacturer has a duty to the generic consumer under state common law principles. *See, e.g.*, *In re Darvocet*, 756 F.3d at 937 ("There are two analytical avenues by which a state's highest court would determine whether Plaintiffs have stated viable misrepresentation claims against Brand Manufacturers under applicable state law.")

A minority of courts, however, deviate from *Foster* for a number of reasons.[4] For example, the *Foster* court's understanding of generic drug manufacturers' responsibility for their labels was invalidated by *Mensing*. The *Foster* court noted that generic manufacturers "are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval[,]" *Foster*, 29 F.3d at 170, but the Supreme Court later held that generic manufacturers cannot strengthen or change their warnings and labels unilaterally because it would violate the federal "duty of sameness." *See Mensing*, 564 U.S. at 618–19.

Following *Mensing*, the Supreme Court of California found that the unique circumstances of the prescription drug market in which, "one entity's misrepresentations about its own product foreseeably and legally contribute[] substantially to the harm

---

[4] *See, e.g.*, *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 718 (N.D. Ill. 2014) (explaining that the *Foster* court incorrectly "analyzed the complaint as though it presented an indeterminate tortfeasor problem"); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 707 (D. Vt. 2010) (distinguishing cases that agreed with *Foster* on the basis that many had statutes defining the scope of permissible actions against manufacturers, whereas "Vermont has not enacted such a statute"); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 110 (Cal. Ct. App. 2008) (describing "countervailing factors" that warrant a different policy analysis than *Foster*).

caused by other entity's product" make warning label liability cases distinct from other products liability cases. *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18, 39 (Cal. 2017) (quotation omitted). The court observed that, "the plaintiffs' claim here is not that [the drug] is defectively designed or inherently dangerous. It is that [the drug]'s warning label failed to mention the risk [of side effects], and that Novartis was responsible for the deficient label. So the alleged fault here lies with Novartis, not with its generic competitors." *Id.* at 33–34.

Courts also distinguish between different states' tort laws, such as the California Supreme Court distinguishing California tort law from Maryland law as interpreted in *Foster*, because "California law does not conflate negligent misrepresentation and strict liability in the manner *Foster* believed was true of Maryland law." *Id.* at 37. As such, the *Novartis* court decided that concerns about holding brand-name defendants liable for harm caused by a generic manufacturer's product were irrelevant, and permitted warning label liability claims to proceed under California tort law. *Id.* at 37–40.[5] Additionally, the

[5] The California Supreme Court also distinguished its relationship to California law from the Fourth Circuit's relationship to Maryland law in *Foster*, noting that federal courts sitting in diversity jurisdiction are "extremely cautious" about recognizing innovative theories under state law. *Novartis*, 407 P.3d at 38. Here, because the Court is sitting in diversity jurisdiction, Defendants assert that "[w]hen given a choice between an interpretation of Illinois law which reasonably restricts liability, and one which greatly expands liability, [the Court] should choose the narrower and more reasonable path (at least until the Illinois Supreme Court tells [the Court] differently)." *Todd v. Societe Bic, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994).

However, based on the existing warning label cases under Illinois law and Illinois products liability and tort precedent as discussed below, the Court's decision does not greatly expand liability, it merely applies Illinois law. Additionally, the Court notes that cases such as *Dolin v.*

court found that "California law places greater weight on foreseeability in the duty analysis" than Maryland law, and "[does] not narrowly construe the kinds of relationships that must exist" to impose a duty to prevent injuries from a defendant's own conduct. *Id.* at 38–39. The court therefore found a duty existed between the brand-name manufacturer and a generic consumer injured by the brand-name manufacturer's inadequate labeling. *Id.*

The Supreme Court of Alabama also distinguished its common law from Maryland's, and concluded that generic consumers could pursue claims for fraud and misrepresentation in the warning label against brand-name manufacturers. *See Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676-77 (Ala. 2014). Shortly after the *Weeks* decision, however, the Alabama legislature superseded the decision by statute, to require that, "regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based[.]" *Forest Labs., LLC v. Feheley*, 296 So. 3d 302, 312–13 (Ala. 2019) (quoting Ala. Code § 6-5-530(a) (2015)).

SmithKlineBeecham Corp., 62 F. Supp. 3d 705 (N.D. Ill. 2014) already opened the door to Butkiewicz's claims, as evidenced by the inclusion of generics-related claims under Illinois law in this MDL. Illinois tort law has developed to redress all sorts of injuries, and the Court finds that this scenario, although unique, is no exception.

The Court recognizes that the cases rejecting *Foster* and permitting generic consumers to assert claims against brand-name manufacturers for faulty labeling represent a minority view, since courts more often find that the operative state law does not support warning label liability claims. However, the Court finds that whether Butkiewicz's claims are viable relies solely on the contours of Illinois law. With this in mind, the Court turns to Illinois law.

C. Illinois Law

Irrespective of decisions in other jurisdictions, the Court is obligated to apply Illinois law. *See Blankenship v. USA Truck, Inc.*, 601 F.3d 852, 856–57 (8th Cir. 2010) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938)). The Illinois Supreme Court has not directly addressed pharmaceutical warning label liability claims brought by a generic consumer against a brand-name manufacturer. "When there is no state supreme court case directly on point," the role of a federal court sitting in diversity jurisdiction "is to predict how the state supreme court would rule if faced with the same issue[.]" *N. Oil & Gas, Inc. v. EOG Res., Inc.*, 970 F.3d 889, 892 (8th Cir. 2020) (quoting *Blankenship,* 601 F.3d at 856).

1. *Smith v. Eli Lilly*

Although the Illinois Supreme Court has not addressed whether brand-name drug manufacturers are subject to warning label liability, Defendants argue that such claims are precluded by *Smith v. Eli Lilly*, 560 N.E.2d 324 (Ill. 1990). In *Smith*, the plaintiff faced

the issue of indeterminate tortfeasors because she could not identify the actual manufacturer of the drug ingested. *Id.* at 326. Instead, the plaintiff argued that each defendant's respective market share should serve as a proxy for causation. *Id.* The Illinois Supreme Court rejected this "market share liability" theory because "[a] fundamental principle of tort law is that the plaintiff has the burden of proving by a preponderance of the evidence that the defendant caused the complained-of harm or injury; mere conjecture or speculation is insufficient proof. . . . Likewise, to recover under strict liability the plaintiff must establish some causal relationship between the defendant and the injury-producing agent." *Id.* at 328. In other words, the "identification element of causation" limits the scope of potential liability in products liability cases. *Id.* at 329.

Defendants posit that the *Smith* plaintiff's theory of market share liability is functionally identical to Butkiewicz's theory of Defendants' warning label liability, and therefore his claims must fail for lack of product identification. Contrary to Defendants' position, it is difficult to see how the two theories of liability are functionally identical. The plaintiff in *Smith* had to rely on market share liability because she could not determine which entity was responsible for the harmful conduct due to the passage of time and other factors such as poor record-keeping. Here, Butkiewicz knows exactly which entity is responsible for the allegedly harmful conduct: the Bayer Defendants. Defendants created the label that allegedly caused Butkiewicz's doctor to prescribe ciprofloxacin. Butkiewicz has identified the defendant and duty owed: Defendants' exclusive

responsibility for the warnings that must accompany both brand-name Cipro and generic ciprofloxacin.

Furthermore, *Smith*'s duty-limiting principle does not apply to Butkiewicz's claims. The *Smith* court held that "[e]ach manufacturer owes a duty to plaintiffs who will use its drug or be injured by it. However, the duty is not so broad as to extend to anyone who uses the type of drug manufactured by a defendant[.]" *Id.* at 343 (citation omitted). *Smith* involved a plaintiff alleging liability based upon physiological harm caused by ingesting the defendants' drug. Here, Butkiewicz does not seek to hold Defendants liable because he used the type of drug they manufacture. Rather, he seeks to hold Defendants liable because he relied on a warning label that Defendants undisputedly wrote—even if that label was affixed to a different product. As such, the Court finds that *Smith* does not preclude Butkiewicz's warning label claims.

The Northern District of Illinois, considering allegations similar to Butkiewicz's, agreed that *Smith* presents a materially different fact pattern under Illinois law. In *Dolin v. SmithKlineBeecham Corp.* the plaintiff filed a lawsuit against defendant GlaxoSmithKline ("GSK"), the manufacturer of brand name Paxil, for failure to warn of a risk of suicide after her late-husband was prescribed Paxil but received the generic equivalent, paroxetine. 62 F. Supp. 3d 705, 709–10 (N.D. Ill. 2014), *rev'd on other grounds*

sub. nom., *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018).[6] The *Dolin* court rejected GSK's argument that *Smith* required dismissal, saying that, although "[t]aken out of context, language in product identification cases like *Smith* . . . may well appear to support GSK's argument," the problem of indeterminate tortfeasors was not at issue in the case at hand. *Id.* at 718. Therefore, "to suggest that the question actually raised here is simply whether GSK may be held liable for injuries caused by a product that [the generic company] manufactured is incomplete and misleading." *Id.* Rather, the question is "whether GSK, though not the pill's manufacturer, may nevertheless be held liable for tortious conduct that was extrinsic to the manufacturing process and that contributed to Plaintiff's injury." *Id.*

Defendants urge the Court to disregard *Dolin* and instead adopt the Sixth Circuit's analysis of Illinois law. The Sixth Circuit suggested that generics warning label claims brought against brand-name manufacturers would fail under Illinois law for lack of product identification pursuant to *Smith*. *See In re Darvocet*, 756 F.3d at 944 (citing *Smith*, 560 N.E.2d at 328).[7]

---

[6] The Seventh Circuit dismissed the case on preemption grounds because the warning which the plaintiff claimed GSK should have included was previously rejected by the FDA, so GSK could not simultaneously comply with state law, requiring it to strengthen the label, and federal law, which rejected the strengthened version. *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 813–16 (7th Cir. 2018). The Seventh Circuit declined to comment on the district court's analysis on the duty question because the preemption issue was decisive. *Id.*

[7] *See also In re: Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924, 2020 WL 7866660, at *19–20 (S.D. Fla. Dec. 31, 2020) (finding that the Sixth Circuit's holding in *In re Darvocet* is "sound and more persuasive" than *Dolin*). Because the Southern District of Florida relied solely on the Sixth

The Court declines. The Sixth Circuit and Defendants misunderstand the type of injury a generic consumer can attribute to a brand-name manufacturer through warning label liability. Butkiewicz, like the plaintiff in *Dolin*, did "not [bring] suit against [the drug company] for tortious conduct committed strictly as a manufacturer of products." *Dolin*, 62 F. Supp. 3d at 713. Rather, Butkiewicz seeks to recover for injuries related to ciprofloxacin's warning label and product information, authored by Defendants, which failed to inform him and his prescribing physician about the risks of peripheral neuropathy. That Defendants "did not manufacturer the pill [Mr. Butkiewicz] ingested is largely immaterial on this point. A problem with [ciprofloxacin]'s warning label and design will impact the name-brand version . . . and any generic versions of the drug equally." *Id.* at 715. Thus, fault for any alleged injury related to ciprofloxacin's label can be attributed to Defendants. *Accord Novartis*, 407 P.3d at 34–35.

Because the Court finds that *Smith* does not preclude warning label liability claims against Defendants, the Court examines whether the Illinois Supreme Court would dismiss or permit Butkiewicz's claims following the two-part analysis from *Foster* noted above: first, whether Illinois law would require his negligence and fraud claims to be treated as strict product liability claims, and second, if those claims are distinct, whether Defendants owed a duty to Butkiewicz.

Circuit's analysis rather than examining the underlying Illinois caselaw, the recent *In re Zantac* decision does not affect the Court's analysis of and disagreement with *In re Darvocet* as described herein.

2. Whether Negligence and Fraud Claims Are Distinct from Product Liability Claims

As part of its analysis of *Smith*, the Sixth Circuit noted that, "[w]hile Illinois does not have a product liability statute, its case law indicates that Plaintiffs' misrepresentation claims would be construed as product liability claims and fail for lack of product identification" since Illinois law requires a plaintiff to "identify the supplier of the product and establish a causal connection between the injury and the product." *In re Darvocet*, 756 F.3d at 944 (quoting *York v. Lunkes*, 545 N.E.2d 478, 480 (1989)). But a closer look at Illinois case law, including cases the Sixth Circuit relied on, reveals that Illinois law does not require the Court to construe Butkiewicz's claims as products liability claims.

First, the Sixth Circuit relied on *Smith v. Eli Lilly* and *York v. Lunkes* to conclude that Illinois law requires that warning label claims be treated as de facto product liability claims. *In re Darvocet*, at 756 F.3d at 944. Yet, like *Smith*, *York* is a case in which the plaintiff could not identify the precise wrongdoer—an issue of indeterminate tortfeasors—which is not an issue currently before the Court, and therefore these two Illinois decisions do not compel the Court to construe Butkiewicz's negligence and fraud claims as products liability claims. *Cf. Dolin*, 62 F. Supp. 3d at 716–17 (noting that generic warning label claims and indeterminate tortfeasor claims involve two "facially similar, but fundamentally distinct" tort issues).

Moreover, the Illinois Supreme Court has recognized that injuries caused by use of a product and injuries caused by faulty information provided with the product are legally

distinct. For example, in *Board of Education of City of Chicago v. A, C and S, Inc.*, the Supreme Court of Illinois first addressed products liability claims, and then separately analyzed claims for negligent and fraudulent misrepresentation. 546 N.E.2d 580, 585–95 (Ill. 1989). The court explained that negligent misrepresentation liability "extends to any defendant 'who, in the course of an activity which is in furtherance of his own interests, undertakes to give information to another, and knows or should realize that the safety of the person of others may depend upon the accuracy of the information.'" *Id.* at 593 (quoting Restatement (Second) of Torts § 311, Explanatory Notes, cmt. b, at 106 (1965)).

Although *Board of Education* was decided outside the pharmaceutical drug context, it is nonetheless indicative that, in a product-related case, Illinois law (1) does not require negligent misrepresentation claims to be treated as de facto products liability claims, and (2) analyzes negligent misrepresentation claims based on a defendant's conduct in providing information about a product, not just their conduct in manufacturing or distributing the product.

As such, the Court finds that Illinois law does not preclude Butkiewicz's claims because it does not require that warning label liability claims be construed as products liability claims, and Butkiewicz's claims need not fail because Defendants did not manufacture the pill he ingested. Thus, Butkiewicz may assert claims specifically related to injuries caused by Defendants' labeling separately from injuries caused by the drug itself. Accordingly, the Court will proceed to part two of the warning label liability

analysis: whether Defendants owe a duty of care to a generic consumer like Butkiewicz when creating the label for Cipro and ciprofloxacin.

D. Defendants' Duty to Generic Consumers

The "touchstone of [the Court's] duty analysis is to ask whether a plaintiff and a defendant stood in such a relationship to one another that [Illinois] law imposed upon the defendant an obligation of reasonable conduct for the benefit of the plaintiff." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1097 (Ill. 2012) (emphasis omitted). An analysis of such a relationship involves four factors: (1) the reasonable foreseeability of the injury, (2) the likelihood of the injury, (3) the magnitude of the burden of guarding against the injury, and (4) the consequences of placing that burden on the defendant. *Id.* Here, the foreseeability, burden, and consequences of the duty are the most pertinent factors.[8]

A generic drug manufacturer is required to use the label and product information created by the brand-name manufacturer. *See Mensing*, 564 U.S. at 618. It is therefore foreseeable that misconduct by Defendants with respect to the warning label could result in injury to a consumer who uses the generic drug.

[8] As to the second element, since the labels on brand-name and generic drugs must be the same at all times, *Mensing*, 564 U.S. at 618–19, the likelihood of injury based on the warning label is the same for consumers of brand-name Cipro as for consumers of generic ciprofloxacin. Thus, the likelihood of injury is neutral as to whether the brand-name manufacturer has a duty to generic consumers who rely on their label.

The *In re Darvocet* court, by contrast, concluded that the Illinois Supreme Court would not find that brand-name manufacturers owe generic consumers a duty because "generic consumers' injuries are not the foreseeable result of the brand manufacturer's conduct, but of the laws over which the brand manufacturers have no control." 756 F.3d at 944. It is true that Defendants are responsible for ciprofloxacin's warning label only by virtue of federal law. Yet, if Defendants' conduct when creating the warning label is negligent or fraudulent, then injuries from the label, whether it is affixed to Cipro or ciprofloxacin, are a foreseeable result of their conduct with respect to labeling. Because Illinois law does not require a direct relationship between the parties for a duty to exist, the Court finds that an injury to generic consumers is sufficiently foreseeably. *See Simpkins*, 965 N.E.2d at 1097 (finding that a "direct relationship" between parties "is not an additional requirement to establishing a duty"); *accord Novartis*, 407 P.3d at 37–38.

The burden of Defendants' duty to guard against injury to generic consumers from their labeling, and the consequences of that burden, are minimal. Defendants' duty to Butkiewicz or any other generic consumer only requires that they exercise the same level of care as when labeling their brand-name drugs. Thus, the consequence is merely reinforcement of Defendants' pre-existing duty to provide adequate warning labels. So long as warning label liability claims are restricted to injuries caused by a deficient label, imposing a duty does not present grave consequences for Defendants. Rather, permitting Butkiewicz to assert negligence and fraud claims against Defendants "simply allows [the

plaintiff] to attempt to recover for deficiencies in [the drug's] label from the one entity, under federal law, that has unilateral ability to strengthen the label." *Garner v. Johnson & Johnson*, No. 16-1494, 2017 WL 6945335 at *7 (C.D. Ill. Sept. 6, 2017).

The Court concludes that, under Illinois law, Defendants had a duty to Butkiewicz when creating the ciprofloxacin warning label because he foreseeably relied on their warning label, even though it was affixed to a product Defendants did not manufacture. However, this is a limited duty because the relationship between Defendants and Butkiewicz only relates to ciprofloxacin's label. Thus, any recovery shall be fashioned accordingly to redress only injuries caused by the label. The Court therefore proceeds to analyze Butkiewicz's specific claims.

E. Butkiewicz's Claims

1. Strict Liability and Products Liability – Failure to Warn

As to Butkiewicz's strict liability and product liability – failure to warn claims, the Court agrees with Defendants that Butkiewicz cannot state a claim against Defendants. Under Illinois law, to recover based on strict liability in a products liability action, a plaintiff must allege that "the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control." *Mikolajczyk v. Ford Motor Co*., 901 N.E.2d 329, 335 (Ill. 2008). Strict liability may only be imposed against entities in the "distributive chain" for a product, such as manufacturers, distributors, and retailers. *See Dolin*, 62 F. Supp. 3d at 721 (citing *Hammond v. N. Am. Asbestos Corp*., 454 N.E.2d 210, 216 (Ill. 1983)). Because

Defendants are not in the distributive chain for generic ciprofloxacin, Butkiewicz has failed to state a strict liability claim.

Likewise, the Court will dismiss Butkiewicz's claim for product liability – failure to warn. It appears that Butkiewicz's failure to warn claim is a negligent products liability claim.[9] "[A] plaintiff may plead a product liability negligence claim by pointing to a way in which the product was unreasonably dangerous and defendant failed to warn of its dangerous propensity." *Garner*, 2017 WL 6945335, at *8 (quotation omitted).[10] In other words, like a strict liability claim, a negligent products liability claim requires an analysis of the condition of the product. As such, the Court finds that permitting Butkiewicz's product liability – failure to warn claim to proceed would run afoul of product liability principles because Defendants are outside the chain of distribution for ciprofloxacin.[11] The Court will therefore dismiss Butkiewicz's claim for product liability – failure to warn.

---

[9] Illinois recognizes both negligent and strict products liability, which are differentiated by whether the focus is on the condition of a product for strict liability or the condition of a product plus a defendant's fault for negligence. *See Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 263–64 (Ill. 2007).

[10] *See also Great N. Ins. Co. v. Amazon.com, Inc.*, No. 19-684, 2019 WL 3935038, at *2 (N.D. Ill. Aug. 20, 2019) ("[A] negligent failure to warn claim is viable only if the defendant knew or should have known of the danger 'at the time the product left its control.'" (quoting *Modelski v. Navistar Int'l Transp. Co*., 707 N.E.2d 239, 246 (Ill. App. 1999)).

[11] The Court notes that, on this point, its conclusion differs from the *Dolin* court's holding. *See Dolin*, 62 F. Supp. 3d at 720–21. The Court finds that the products liability principles which the *Dolin* court itself relied on to dismiss strict liability claims should also apply to negligent product liability claims. Although negligent product liability claims depend on a defendant's duty and conduct, and are analyzed within the framework of common law negligence, they also depend on the condition of the product. *See, e.g.*, *Rose v. Vanity Fair Brands, LP*, No. 13-167, 2013 WL

2. Breach of Express and Implied Warranty

To state a claim for breach of express warranty under Illinois law, "the terms of the express warranty must be stated or attached to the complaint, and failure to do so renders the claim invalid." *Bd. of Educ.*, 546 N.E.2d at 595 (citations omitted). Illinois law treats express warranty claims as contract claims and typically requires privity between the parties for viable breach of express warranty claims. *See Collins Co. v. Carboline Co.*, 532 N.E.2d 834, 841–42 (Ill. 1988). The language of the ciprofloxacin warning label and product information, the express warranty at issue, is included in the MDL Master Complaint. However, because the parties are not in privity, the Court finds that Butkiewicz has failed to state a claim for breach of express warranty.

Butkiewicz also claims breach of the implied warranty of merchantability. Under Illinois law, implied breach of warranty claims are treated as contract claims and require privity between the parties. *Szajna v. General Motors Corp.*, 503 N.E.2d 760, 766–67 (Ill. 1986). There is no contract between Butkiewicz and Defendants, and Defendants did not sell the ciprofloxacin to Butkiewicz. Accordingly, the Court finds that Butkiewicz cannot state a claim for breach of the implied warranty of merchantability.

1752705, at *3 (N.D. Ill. Apr. 23, 2013) (citing *Calles*, 864 N.E.2d at 263 and *Blue v. Environmental Engineering, Inc.*, 828 N.E.2d 1128, 1141 (2005)). As the *Dolin* court noted, the warning label created by Defendants is not a product; ciprofloxacin is the product. *See Dolin*, 62 F. Supp. 3d at 721–22. Therefore, because Defendants are outside the distributive chain, the Court finds that they cannot be liable for negligent products liability, so long as the claim depends in part on the condition of a product Defendants did not manufacture or distribute.

3. Negligence and Negligent Misrepresentation

Unlike his products liability claims, Butkiewicz's negligence and negligent misrepresentation claims do not require Defendants to be in the chain of distribution for ciprofloxacin. Rather, the claims turn on whether Defendants had a duty to Butkiewicz under Illinois law to guard against injury from the information Defendants provided about ciprofloxacin. Because the Court finds that Defendants did have a duty to Butkiewicz, the Court will analyze whether Butkiewicz has stated a negligence claim. To state a negligence claim, Butkiewicz must allege facts that establish a breach of a duty of care owed by Defendants and an injury proximately caused by that breach. *See Simpkins*, 965 N.E.2d at 1096.

Butkiewicz alleges that Defendants had a duty to adequately inform him and his physician of known side effects from ciprofloxacin. Yet, despite knowing of the risk of peripheral neuropathy, Defendants recklessly concealed the information from Butkiewicz by omitting it from the warning label for Cipro and ciprofloxacin, thereby breaching their duty to disclose. Because Butkiewicz relied on the ciprofloxacin warning label, he failed to recognize neuropathy symptoms as a side effect of ciprofloxacin, resulting in injury caused by Defendants' breach. Accepting the factual allegations as true, the Court finds that Butkiewicz states a claim for negligence related to the warning labels on ciprofloxacin.

To state a claim for negligent misrepresentation under Illinois law, a plaintiff must show: (1) a false statement of material fact; (2) negligence on the part of the defendant

in ascertaining the truth; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance. *See Bd. of Educ.*, 546 N.E.2d at 591.

Butkiewicz alleges that Defendants made materially false statements about the severity and frequency of the onset of peripheral neuropathy from ciprofloxacin by, among other things, paying consultants to falsely tout its benefits and downplay its risks in scientific literature. Butkiewicz alleges Defendants should have known through due care that the statements were false, Defendants acted recklessly and intentionally, that Butkiewicz and other plaintiffs relied on Defendants' statements, and Butkiewicz was injured. Therefore, the Court finds that Butkiewicz has also stated a claim for negligent misrepresentation.

4. Fraud and Fraudulent Concealment

Under Illinois law, to state a claim for common law fraud, a plaintiff must allege that defendants (1) made a false statement of material fact, (2) knew the statement was false, and (3) intended that the statement induce the plaintiff to act; and that the plaintiff (4) relied on the truth of the statement, and (5) suffered damages resulting from reliance on the statement. *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 591 (Ill. 1996). For fraudulent concealment, a plaintiff must allege that a defendant concealed a material fact when they were under a duty to disclose that fact to the plaintiff. *Id.* at 593. A duty to

disclose could be based on a fiduciary or confidential relationship, or because the defendant otherwise is in a position of influence of superiority over the plaintiff. *Id.*

As discussed above, Illinois law does not compel the Court to construe all of Butkiewicz's claims as product liability claims, and Defendants have a duty to Butkiewicz to guard against injury from reliance on the ciprofloxacin warning label. As such, the Court finds that claims for fraud and fraudulent concealment related to the warning label are cognizable and turns to the sufficiency of the allegations under Federal Rule of Civil Procedure 9(b). *Cf. Garner*, 2017 WL 6945335, at *8 (dismissing fraud and fraudulent concealment claims because the plaintiff did not plead them with sufficient particularity).

Rule 9(b) requires fraud-based claims to be pleaded with particularity. Fed. R. Civ. P. 9(b). The "plaintiff must specifically allege the circumstances constituting fraud, including such matters as the time, place and contents of false representations[.]" *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001) (cleaned up). In other words, "the complaint must identify the who, what, where, when, and how of the alleged fraud." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006) (quotation omitted).

Butkiewicz, through the MDL Master Complaint, provides detailed allegations about the contents and timing of Defendants' allegedly fraudulent conduct, such as efforts to downplay the significance of a study about ciprofloxacin's serious side effects in 2001, identifies, by name, paid medical consultants and Bayer employees who allegedly

made false statements and representations and quotes their statements, and explains how and why Defendants were aware of risks from the drug but chose to aggressively market it nonetheless. Therefore, the Court finds that Butkiewicz has plausibly stated claims for fraud and fraudulent concealment.

5. Illinois Consumer Protection

To state a claim for a violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, Ill. Comp. Stat. 505 et seq., a plaintiff must allege "(1) a deceptive act or practice by the defendant, (2) the defendant's intent that the plaintiff rely on the deception, (3) the occurrence of the deception in the course of conduct involving trade or commerce, and (4) actual damage to the plaintiff (5) proximately caused by the deception." *Avery v. State Farm Mut. Auto. Ins. Co.*, 835 N.E.2d 801, 850 (2005).

Butkiewicz's allegations plausibly satisfy the five elements by stating that Defendants deceived consumers by covering up information about ciprofloxacin's serious side effects by failing to include a warning about peripheral neuropathy on the label, Defendants intended consumers and physicians to rely on their misrepresentations, and Butkiewicz relied on the inadequate warning label, leading to undiagnosed peripheral neuropathy. Therefore, the Court finds that Butkiewicz has plausibly stated a claim that Defendants violated Illinois consumer protection law.

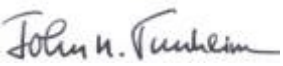
CONCLUSION

Butkiewicz seeks to redress injuries caused by the deficient warning label on ciprofloxacin, which Defendants authored. Under Illinois law, the Court is not required to treat Butkiewicz's negligence, negligent misrepresentation, fraud, fraudulent concealment, and consumer protection claims as product liability claims, and these claims therefore do not fail simply because Defendants did not manufacture the drug Butkiewicz consumed. Defendants had a duty to Butkiewicz to exercise reasonable care in the course of creating the warning label for generic ciprofloxacin. The Court acknowledges that similar claims have gained little traction in other jurisdictions. However, the Court finds that warning label claims against a brand-name drug manufacturer are viable pursuant to Illinois law, insofar as a generic consumer seeks to recover for injuries caused by an allegedly deficient label.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss [Docket No. 34] is **GRANTED** as to Counts I, II, IV, and V, and **DENIED** as to all other Counts. Counts I, II, IV, and V are **DISMISSED with prejudice.**

DATED: February 4, 2021
at Minneapolis, Minnesota.



JOHN R. TUNHEIM
Chief Judge
United States District Court